K011229 JUL 11 2001

DeVilbiss 9000 Series CPAP 510(k) Summary

Submitter's Name:	**Sunrise Medical HHG, Inc. Respiratory Products Division 100 DeVilbiss Drive Somerset, PA 15501-0635**
Contact Person:	**James Froehlich (814)-443-7692**
Date Prepared:	**April 20, 2001**
Trade or Proprietary Name:	**DeVilbiss 9000 Series CPAP**
Common or Usual Name:	**Nasal CPAP with Remote Control Module**
Model Number:	**Model 9001 CPAP and Remote Control Module**
Establishment Registration Number:	**2515872**
Device Classification:	**Class II**
Classification Name:	**Ventilator, Non-continuous**
Legally Marketed Predicate:	**DeVilbiss Model 7353 CPAP with Remote Control Module; 510(k) #935979**

Description of Device:

The Model 9001 CPAP is a standard Continuous Positive Airway Pressure (CPAP) device with a low-pressure delay function which permits the patient to attain sleep, before the prescription pressure is applied. The prescription pressure is set such that it provides an "air splint" to the patient's airway, via a flexible tube and nasal mask. The prescription pressure is set by a clinician or medical products dealer to a physician-determined level sufficient to prevent Obstructive Sleep Apnea (OSA). The delay pressure and time of delay may be included in the prescription. The Model 9001 also has an interface with a remote control module, which is described below. The data presented by the on-board LCD can be repeated in the remote control module for use in the clinical setting.

The Remote Control Module is an electronic controller which can be connected to the Model 9001 CPAP by a removable umbilical. It is used by the clinician or the medical products dealer to set the prescription pressure, the delay pressure and the delay time and to read the memory of the Model 9001 CPAP to determine how many hours the patient has used the CPAP ("compliance" data).

Statement of Intended Use

This product has been designed for the treatment of obstructive sleep apnea, specifically for use in the adult population.

Conclusion

Comparison of characteristics and performance of the DeVilbiss Model 9001 CPAP and the Remote Control Module with the predicate device demonstrate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Mr. James P. Froehlich
Sunrise Medical HHG, Inc.
Respiratory Products Division
100 DeVilbiss Drive
Somerset, PA 15501-0635

Re: K011229
DeVilbiss 9000 Series CPAP, Model 9001
Regulation Number: 868.5905
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: June 7, 2001
Received: June 11, 2001

Dear Mr. Froehlich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011229

Device Name DeVilbiss Model 9001 CPAP with DeVilbiss Remote Control Module

Indications For Use:

This product has been designed for the treatment of obstructive sleep apnea, specifically for the adult patient population.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, [redacted] Devices
510(k) Number K011229

X Prescription use or ___ Over-the-counter use